

Exhibit 3



UNITED STATES DEPARTMENT OF COMMERCE
Patent and Trademark Office

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SERIAL NUMBER	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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07/532,267 06/01/90 LANDOLFI

N 11823-18

EXAMINER

DRAPER, G

ART UNIT

PAPER NUMBER

1812

13

DATE MAILED:

02/10/93

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ONE MARKET PLAZA
SAN FRANCISCO, CA 94105

This is a communication from the examiner in charge of your application.
COMMISSIONER OF PATENTS AND TRADEMARKS

☒ This application has been examined ☒ Responsive to communication filed on 9-24-92 This action is made final.

A shortened statutory period for response to this action is set to expire 3 month(s), — days from the date of this letter.
Failure to respond within the period for response will cause the application to become abandoned. 35 U.S.C. 133

Part I THE FOLLOWING ATTACHMENT(S) ARE PART OF THIS ACTION:

- | | |
|---|--|
| 1. <input checked="" type="checkbox"/> Notice of References Cited by Examiner, PTO-892. | 2. <input type="checkbox"/> Notice re Patent Drawing, PTO-948. |
| 3. <input type="checkbox"/> Notice of Art Cited by Applicant, PTO-1449. | 4. <input type="checkbox"/> Notice of Informal Patent Application, Form PTO-152. |
| 5. <input type="checkbox"/> Information on How to Effect Drawing Changes, PTO-1474. | 6. <input type="checkbox"/> _____ |

Part II SUMMARY OF ACTION

1. ☒ Claims 1-24 are pending in the application.
Of the above, claims 16-22 and 24 are withdrawn from consideration.
2. ☐ Claims _____ have been cancelled.
3. ☐ Claims _____ are allowed.
4. ☒ Claims 1-15 and 23 are rejected.
5. ☐ Claims _____ are objected to.
6. ☒ Claims 1-24 are subject to restriction or election requirement.

7. ☒ This application has been filed with informal drawings under 37 C.F.R. 1.85 which are acceptable for examination purposes.
8. ☐ Formal drawings are required in response to this Office action.
9. ☐ The corrected or substitute drawings have been received on _____. Under 37 C.F.R. 1.84 these drawings are ☐ acceptable. ☐ not acceptable (see explanation or Notice re Patent Drawing, PTO-948).
10. ☐ The proposed additional or substitute sheet(s) of drawings, filed on _____ has (have) been ☐ approved by the examiner. ☐ disapproved by the examiner (see explanation).
11. ☐ The proposed drawing correction, filed on _____, has been ☐ approved. ☐ disapproved (see explanation).
12. ☐ Acknowledgment is made of the claim for priority under U.S.C. 119. The certified copy has ☐ been received ☐ not been received
☐ been filed in parent application, serial no. _____; filed on _____
13. ☐ Since this application appears to be in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11; 453 O.G. 213.

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1. The following objections and rejections have been withdrawn.
-regarding a proper title.

-the 35 USC 112 for "growth like"

-portions of the 35 USC 101 aspect of the previous rejection, and only certain portions of the previous 35 USC 112/1st aspect of this rejection not herein restated

-the requirement for a deposit

-the alternative 35 USC 112 1st/2nd paragraph rejection.

2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

3. Applicant's arguments filed 9-28-92 have been fully considered but they are not deemed to be persuasive.

4. The following is a quotation of the first paragraph of 35 U.S.C. § 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The specification is objected to under 35 U.S.C. § 112, first paragraph, as failing to provide an enabling disclosure and for lack of demonstrated utility.

Claims 11-12 and 14 are rejected under 35 USC 101 for lack of demonstrated utility, and these claims are rejected under 35 U.S.C. § 112, first paragraph, for the reasons set forth in the

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objection to the specification.

The objection and the rejections are maintained only with regard to these broad claims for the reasons set forth in the previous office action at pages 5-6. Most of applicants arguments were directed to the IL-2-Ig immunoligands; however, these claims are broadly directed to any growth factor -Ig immunoligand. The preparation of one such product is not predictive and enabling for the broad scope of growth factors and Ig fusions. The presence or absence of other growth factors on surface of various cells is not clear; nor whether the respective ligand-receptor interaction is present and readily associated with the desired condition to be treated; especially for cell-lytic activity or ADCC.

5. Claim 8 is rejected under 35 U.S.C. § 112, fourth paragraph, as being of improper dependent form for failing to further limit the subject matter of a previous claim.

Claim 1, from which claim 8 depends, has been amended to recite IL-2 as the ligand therefore the claim is not further limiting.

6. Claims 11-12 and 14 are rejected under 35 U.S.C. § 102(a or b) as anticipated by or, in the alternative, under 35 U.S.C. § 103 as obvious over Tranuechker et al or Schnee et al or von Wussow.

These rejections are maintained for the reasons set forth in

the previous office action. Applicant has merely stated the make-up of the immunoligands of the prior art, and has further argued their patentability relative to IL-2; however these claims are broadly directed to immunoligands and are not restricted to IL-2. Accordingly, they would not be expected to possess the same kind of activity as the IL-2--immunoligand. Applicant has not proffered evidence or sufficient arguments to support their position that the prior art immunoligands do not bind to ~~the~~ respective cell surface receptors, possess complement-mediated lysis, or ADCC. Therefore, this appears to represent unsupported allegations.

It is believed that all pertinent arguments have been answered.

8. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Claims 1-10, 13, 15 and 23 are rejected under 35 U.S.C. § 103 as being unpatentable over Von Wussow et al.

Even though the claims have been amended to limit ^{them} to the immunoligand comprising IL-2 as the ligand component, the claims are still prima facie obvious over the art because IL-2 is specifically taught as being usable in the immunoligand construct, therefore, one having ordinary skill in the art would have used the teachings therein to construct immunoligands with any one of the disclosed ligands. Since the prior art listing of IFN and

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IL-2 implies that they would be functionally equivalent in such immunoligand, the skilled artisan would have reasonably expected that either of these cytokine ligands could be used in the immunoligand for similar functions. Contrary to applicants assertion, it has been well known in the art that IFN mediate ADCC and complement-mediated lysis. Furthermore, the resulting biological activity of the various immunoligands is not the controlling issue of obviousness, but rather, whether the ^{prior} art disclose the product per se or render it obvious. Herein the construction of IL-2 immunoligands are obvious from the art.

The prior art listed on the PTO-892 is cited as of interest to show related art.

Applicant's amendment necessitated the new grounds of rejection. Accordingly, **THIS ACTION IS MADE FINAL**. See M.P.E.P. § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 C.F.R. § 1.136(a).

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A SHORTENED STATUTORY PERIOD FOR RESPONSE TO THIS FINAL ACTION IS SET TO EXPIRE THREE MONTHS FROM THE DATE OF THIS ACTION. IN THE EVENT A FIRST RESPONSE IS FILED WITHIN TWO MONTHS OF THE MAILING DATE OF THIS FINAL ACTION AND THE ADVISORY ACTION IS NOT MAILED UNTIL AFTER THE END OF THE THREE-MONTH SHORTENED STATUTORY PERIOD, THEN THE SHORTENED STATUTORY PERIOD WILL EXPIRE ON THE DATE THE ADVISORY ACTION IS MAILED, AND ANY EXTENSION FEE PURSUANT TO 37 C.F.R. § 1.136(a) WILL BE CALCULATED FROM THE MAILING DATE OF THE ADVISORY ACTION. IN NO EVENT WILL THE STATUTORY PERIOD FOR RESPONSE EXPIRE LATER THAN SIX MONTHS FROM THE DATE OF THIS FINAL ACTION.

Draper/tf
February 02, 1993



GARNETTE D. DRAPER
PRIMARY EXAMINER
ART UNIT 186